

Notice of Allowability

Application No.

09/060,409

Examiner

Anne-Marie Falk, Ph.D.

Applicant(s)

SAH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the after final amendment submitted 12/8/03.
 2. ☒ The allowed claim(s) is/are 6-16, 47, 48, 50, 51, 53, 60-69 and 74-78.
 3. ☒ The drawings filed on 08 December 2003 are accepted by the Examiner.
 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Anne-Marie Falk
Anne-Marie Falk, Ph.D.
Primary Examiner
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EXAMINER'S AMENDMENT

The amendment filed December 8, 2003 has been entered. Claims have been amended. Claims 49, 52, 54-59, and 70-73 have been cancelled.

Accordingly, Claims 6-16, 47, 48, 50, 51, 53, 60-69, and 74-78 remain pending.

The following formal Examiner's amendment was made February 10, 2004.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on February 10, 2004, Lawrence Graham requested an extension of time for TWO MONTH(S) and authorized the Director to charge Deposit Account No. 16-1150 the required fee of \$840.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the Claims:

51. A method according to claim 50, wherein [//the//] said cell is a conditionally-immortalized rat or human dorsal root ganglion progenitor cell, and wherein [//the//] said cell is cultured in the presence of one or more differentiating agents.

60. A method of identifying an agent that modulates the level or activity of a protein produced by a dorsal root ganglion progenitor cell, comprising:

(a) contacting a cell produced according to the method of claim 6 with a candidate agent;

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(b) determining the level or activity of said protein in the presence of said agent and in the absence of said agent; and

(c) comparing the level or activity of said protein in the presence of said agent with the level or activity of said protein in the absence of said agent,

wherein if said level or activity of said protein in the presence of said agent is different than the level or activity of said protein in the absence of said agent, said agent is identified as an agent that modulates the level or activity of a protein produced by a dorsal root ganglion progenitor cell.

61. A method for identifying an agent that modulates the level or activity of a protein produced by a dorsal root ganglion progenitor cell, comprising:

(a) contacting a cell according to claim 12 with a candidate agent;

(b) determining the level or activity of said protein in the presence of said agent and in the absence of said agent; and

(c) comparing the level or activity of said protein in the presence of said agent with the level or activity of said protein in the absence of said agent,

wherein if said level or activity of said protein in the presence of said agent is different than the level or activity of said protein in the absence of said agent, said agent is identified as an agent that modulates the level or activity of a protein produced by a dorsal root ganglion progenitor cell.

66. A method of identifying an agent that affects dorsal root ganglion progenitor cell death, comprising:

(a) contacting a plurality of cells produced according to the method of claim 6 with a candidate agent under conditions that, in the absence of the candidate agent, result in death of said plurality of cells;

(b) determining [a] the number of said plurality of cells that die in the presence of said agent; and

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(c) comparing the number of said plurality of cells that die in the presence of said agent to the number of said plurality of cells that die in the absence of said agent,

wherein if the number of said plurality of cells that die in the presence of said agent is different than said number of said plurality of cells that die in the absence of said agent, said agent is identified as an agent that affects dorsal root ganglion progenitor cell death.

67. A method for screening for an agent that affects dorsal root ganglion progenitor cell death, comprising:

(a) contacting a plurality of cells according to claim 12 with a candidate agent under conditions that, in the absence of the candidate agent, result in death of [the cell] said plurality of cells; and

(b) determining the number of said plurality of cells that die in the presence of said agent; and

(c) comparing the number of said plurality of cells that die in the presence of said agent to the number of said plurality of cells that die in the absence of said agent,

wherein if said number of said plurality of cells that die in the presence of said agent is different than said number of said plurality of cells that die in the absence of said agent, said agent is identified as an agent that affects dorsal root ganglion progenitor cell death.

68. A method for screening for a protein that regulates dorsal root ganglion progenitor cell death, comprising:

(a) altering the level of expression of a protein within a plurality of cells produced according to the method of claim 6;

(b) determining the number of said plurality of cells that die when said level of expression of said protein is altered and when said level of expression is not altered; and

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(c) comparing the number of said plurality of cells that die when said level of expression is altered to the number of said plurality of cells that die when said level of expression is not altered,

wherein if said number of said plurality of cells that die when said level of expression is altered is different than said number of said plurality of cells that die when said level of expression is not altered, said agent is identified as an agent that affects dorsal root ganglion progenitor cell death.

69. A method for screening for a protein that regulates dorsal root ganglion progenitor cell death, comprising:

(a) altering the level of expression of a protein within a plurality of cells according to claim 12;

(b) determining the number of said plurality of cells that die when said level of expression of said protein is altered and when said level of expression is not altered; and

(c) comparing the number of said plurality of cells that die when said level of expression is altered to the number of said plurality of cells that die when said level of expression is not altered,

wherein if said number of said plurality of cells that die when said level of expression is altered is different than said number of said plurality of cells that die when said level of expression is not altered, said agent is identified as an agent that affects dorsal root ganglion progenitor cell death.

74. A method for identifying an agent that modulates the level or activity of a protein produced by a dorsal root ganglion [cell] neuron, comprising:

(a) contacting a cell produced according to the method of claim 47 with a candidate agent;

(b) determining the level or activity of said protein in the presence and absence of said agent; and

(c) comparing the level or activity of said protein in the presence of said agent with the level or activity of said protein in the absence of said agent,

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wherein if said level or activity of said protein in the presence of said agent is different than the level or activity of said protein in the absence of said agent, said agent is identified as an agent that modulates the level or activity of a protein produced by a dorsal root ganglion [cell] neuron.

77. A method for screening for an agent that affects dorsal root ganglion neuronal cell death, comprising:

- (a) contacting a plurality of cells according to the method of claim 47 with a candidate agent under conditions that, in the absence of the candidate agent, result in death of [the cell] said plurality of cells;
- (b) determining the number of said plurality of cells that die in the presence of said agent; and
- (c) comparing the number of said plurality of cells that die in the presence of said agent to the number of said plurality of cells that die in the absence of said agent,

wherein if said number of said plurality of cells that die in the presence of said agent is different than said number of said plurality of cells that die in the absence of said agent, said agent is identified as an agent that affects dorsal root ganglion neuronal cell death.

78. A method for screening for a protein that regulates dorsal root ganglion neuronal cell death, comprising:

- (a) altering the level of expression of a protein within a plurality of cells produced according to the method of claim 47;
- (b) determining a number of said plurality of cells that die when said level of expression of said protein is altered and when said level of expression is not altered; and
- (c) comparing the number of said plurality of cells that die when said level of expression is altered to the number of said plurality of cells that die when said level of expression is not altered,

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wherein if said number of said plurality of cells that die when said level of expression is altered is different than said number of said plurality of cells that die when said level of expression is not altered, said agent is identified as an agent that affects dorsal root ganglion neuronal cell death.

Conclusion

Upon entry of the foregoing amendment, Claims 6-16, 47, 48, 50, 51, 53, 60-69, and 74-78 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to William Phillips, whose telephone number is (571) 272-0548.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER